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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,678	03/10/2004	Fiona Patricia Carney	CL/V-32902A	4167

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CIBA VISION CORPORATION  
PATENT DEPARTMENT  
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EXAMINER

APANIUS, MICHAEL

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/797,678	Applicant(s) CARNEY ET AL.	
	Examiner Michael Apanius	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-64 and 84-91 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 18-20, 34-36, 50-52 and 85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-17, 21-33, 37-49, 53-64, 84 and 86-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20040310, 20041129</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I and Species 3.4 in the reply filed on 7/3/2006 is acknowledged.
2. Claims 2-4, 18-20, 34-36, 50-52 and 85 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/3/2006.
3. The cancellation of claims 65-83 is acknowledged. Currently, claims 1-64 and 84-91 are pending, while claims 2-4, 18-20, 34-36, 50-52 and 85 are withdrawn.

### *Drawings*

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the method steps and the various embodiments of the tear collecting devices must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

6. The disclosure is objected to because of the following informalities: at page 16, line 9, the serial number is missing. Appropriate correction is required.
7. The title of the invention is not sufficiently descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: --Methods for monitoring fertility by measuring the concentration of hormones in tears--.
8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Objections***

9. Claims 11, 15, 25, 32, 43, 57, 64 and 86 are objected to because of the following informalities: at line 2, of claims 11, 25, 43, 57 and 86, it appears that "its" should be -- estrogen--; at claim 15, line 1, "methd" is misspelled; and at line 2 of claims 32 and 64, it appears that --from the onset of menses-- should be added after "day 6". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 9-17, 25-33, 41-49, 57-62, 84 and 86-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Catt et al. (US 6,451,619).

12. Catt discloses a method (column 4, lines 11-20) for determining the fertility status of a current ovulation cycle of a female human, comprising the steps of: (a) monitoring variation in tear concentration of at least one hormone of relevance (LH, estradiol and progesterone: column 9, lines 27-33) to female fertility; and (b) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the transition phase, fertile phase, ovulation, or infertile phase of a menstrual cycle in said

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female human, wherein the step of monitoring is performed by periodically collecting a tear fluid (column 3, lines 60-62) from the female human and then determining the tear concentration of said hormone.

13. In regards to claim 9, the first collecting of tear fluid in the current cycle is made during the interval spanning days 1 to 7 from the onset of menses (column 5, lines 7-29), one of which will correlate with the cessation of menses.

14. In regards to claim 10, the first collecting of tear fluid in the current cycle is made during the interval spanning days 1 to 7 from the onset of menses which includes at least 3 days following the onset of menses.

15. In regards to claim 11, the hormone can be estrogen and wherein a significant increase in estrogen tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period (column 4, lines 42-47).

16. In regards to claim 12, the hormone can be LH and wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, following the cessation of menses, indicates that the female human will no longer be fertile four days hence (column 9, lines 38-50).

17. In regards to claim 13, the hormone can be progesterone (column 9, line 33), wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.

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18. In regards to claims 14 and 15, estrogen and progesterone can be monitored to determine the status of a menstrual cycle of the female human (column 9, lines 27-33).

19. In regards to claim 16, the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is inherently indicative of the onset of the fertile period (see Baird et al. listed under "OTHER PUBLICATIONS").

20. In regards to claim 17, the steps are performed one per day for at least several days preceding and following ovulation (column 30, lines 27-28).

21. In regards to claims 31 and 32, a base concentration value or signal for said hormone in the current cycle is established on day 5 or 6 from the onset of menses (column 5, lines 7-23).

22. In regards to claims 33 and 49, Catt discloses a birth control method that involves avoiding exposure to fertilization beginning at least at the onset of the fertile phase and ending day "+2" relative to the day of actual ovulation (column 6, lines 35-45).

23. In regards to claim 84, Catt discloses testing fertility of a female non-human mammal (column 3, line 53 and column 4, line 12).

24. In regards to the other claims, the limitations are disclosed as noted above.

***Claim Rejections - 35 USC § 103***

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

26. Claims 5-8, 21-24, 37-40 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Catt et al. (US 6,451,619) in view of Abreu (US 6,544,193).

27. Catt does not expressly disclose wearing a contact lens to collect tear fluid.

28. Abreu teaches wearing a contact lens over an 8 hour period and collecting tear fluid at the end of the 8 hour work day for the purpose collecting and analyzing tear fluid in a continuous, comfortable, undisturbed, accurate and low-cost manner (column 42, lines 49-52; column 50, lines 50-64). Abreu further teaches using a soft contact lens (column 96, lines 11-14). Abreu also teaches using a contact lens having a core material (column 41, lines 61-63) that contains a receptor for specifically binding a hormone (column 17, lines 50-51). Note that Abreu teaches that the contact lens can be used to detect ovulation (abstract).

29. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a contact lens as taught by Abreu in the method of Catt in order to collect and analyze tear fluid in a continuous, comfortable, undisturbed, accurate and low-cost manner.



***Conclusion***

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,526,178 discloses a method for obtaining lacrimal fluid. US 5,869,231 discloses a method for reproducibly determining the components of lacrimal fluid. US 2004/0076547, US 2004/0181172 and US 2005/0038329 disclose methods and kits for collecting analytes of interest in tears.


31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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